



Support for the National Accreditation Centre MOLDAC
to successfully undergo the EA peer evaluation process
Twinning Project MD14/ENPI/TR/20



ACTIVITY1.3

TRAINING SESSIONS FOLLOWING THE FINDINGS FROM PREVIOUS ACTIVITIES

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SCOPE OF DOCUMENT

Enable accreditation bodies to better harmonize their application of the standards against which they assess conformity assessment bodies (CABs). The document shall be adopted by accreditation bodies as part of their general rules of operation and will be used by peer evaluation teams in the evaluation of accreditation bodies.





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STRUCTURE OF DOCUMENT

Subdivision into two parts.

Part 1: contains mandatory applications for accreditation body signatories, or applicants for signatory status, to the MLA/MRA.

Part 2: is restricted to Inspection Body accreditation and contains non mandatory applications reflecting best practice, and is intended to assist accreditation bodies with effectively implementing ISO/IEC 17011.





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PART 1: Mandatory Application

In Part 1 Mandatory applications are identified with the letter “M” followed with a reference number that incorporates the related requirements clauses in ISO/IEC 17011.

The term “shall” is used in Part 1 to indicate the provisions reflecting the requirements of ISO/IEC 17011, have to be fulfilled.

The term “should” is used to indicate the applications provided by IAF/ILAC as the suggested tools to satisfy the requirements.





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PART 2: Non - Mandatory Application

The Part 2 provides non-mandatory applications of ISO/IEC 17011 to the accreditation of inspection body services.

Non-mandatory applications in Part 2 are identified with the letter “N” followed with a reference number that incorporates the related requirements clause in ISO/IEC 17011.





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4. Accreditation body

4.1 Legal responsibility

M.4.1.1 Accreditation bodies that are part of government, or are government departments, shall have their status and structure formally documented by government, e.g. Act of Parliament, legislation, administrative act, Memorandum of Understanding or other written statement by an appropriate authority within government, as determined by the government.





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M.4.1.2 In the case where the accreditation body is a separate legal entity within or owned by a larger body, the other parts (the other legal entities) of the larger body are related bodies and therefore provisions of Clause 4.3.7 shall apply to the other entities. In the case where the accreditation body is the same legal entity as the larger body, the provisions of Clause 4.3.6 shall apply to the entire body.

Note: An accreditation body that is part of a larger body may operate under a different name and be recognized nationally and by the MLA/MRA group under that name.





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4.2 Structure

M.4.2.2.1 Accreditation decisions shall not be subject to approval by any other organization or person.

4.3 Impartiality

M.4.3.6.1 *Consultancy services (refer Clause 3.11 of ISO/IEC 17011) and conformity assessment services that CABs perform (as defined in Clause 1 of ISO/IEC 17011) are considered services that can affect impartiality and shall not be offered nor provided by accreditation bodies (irrespective of whether the accreditation body accredits or does not accredit the conformity assessment service).*





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Note: Accreditation bodies may carry out, for example, the following duties that are not considered a threat to impartiality:

- (a) Arranging and participating as a lecturer in training, orientation or educational courses, provided that these courses confine themselves to the provision of generic information that is freely available in the public domain, i.e. they should not provide specific solutions to a CAB in relation to the activities of that organization;
- (b) Adding value during assessments and surveillance visits, e.g. by identifying opportunities for improvement, as they become evident, during the assessment without recommending specific solutions.





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M.4.3.7.1 If the accreditation body and a CAB are both part of the same parent organization (including government) and are separate legal entities (see M.4.1.2 above), the CAB is a related body to the accreditation body and the two bodies shall not directly report to a person or group having operational responsibility for both bodies [Clause 4.3.7 a)].

The accreditation body shall be able to demonstrate, through its documented analysis of the relationship with its related bodies and with its specific implementation of procedures that the CAB receives no advantage, and the accreditation body's impartiality is ensured at all times.





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5.9 Complaints

M.5.9.1 The decisions in response to a complaint should be made by, or reviewed and approved by, individual(s) who are not directly involved in the matters that are the subject of the complaint.

M.5.9.2 The conclusions of the investigation of the complaint shall be communicated to the complainant subject to confidentiality requirements.





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6. Human resources

6.2 Personnel involved in the accreditation process

M.6.2.4.1 Additional competence for assessors/assessment teams for the certification of persons:

- Knowledge in the validation process for certification schemes of persons
- Knowledge regarding written, oral and practical examinations of persons
- Knowledge of the process for the re-certification of persons

6.3 Monitoring

M.6.3.1.1 Personnel to be monitored also includes experts involved in the assessment.





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7.5 Preparation for assessment

M.7.5.7.1 Inspection Body Accreditation

Inspection activities are normally performed on the premises of the client. The requirements of this paragraph refer to the premises of the inspection body and not necessarily to the premises where

inspection activities take place. In inspection, the decisions on the result of the conformity assessment are often made by the inspector on-site and form part of the inspection itself. With reference to the Note on Clause 7.5.7, it is not necessary to visit every inspection site where a decision on conformity is made.





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Guidance to Note to Clause 7.5.7:

In the inspection field, the Note to Clause 7.5.7 should be understood as follows:

(i) Key activities include:

- policy formulation;
- process and/or procedure development;
- process of initial selection of inspectors and, as
- appropriate;
- contract review;
- planning conformity assessments;
- review and approval of conformity assessments.





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(ii) When considering whether a premise is one where key activities are carried out, the accreditation body should consider issues which have an influence on the outcome of inspection. Some of these issues are outlined in Part 2 (non- mandatory) of this document.

M.7.5.7.2 Product Certification Body accreditation

In the product certification field, the Note to Clause 7.5.7 should be understood as follows:

Keys activities include:

- policy formulation and approval;
- process and/or procedure development and approval;
- initial assessment of competence, and approval of technical personnel and subcontractors;





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- control of the monitoring process of competence of personnel and subcontractors and its outcomes;
- contract review including technical review of applications and determining the technical requirements for certification
- activity in new technical areas or areas of limited sporadic activity;
- decision on certification including technical review of evaluation tasks (see IAF GD5:2006 G.4.2.26).

In determining the need to conduct, and for the duration of on-site activities, the accreditation body should also consider the:

- effectiveness of planning conformity assessments;
- availability of records, documents and information that can be reviewed electronically, by web conference or otherwise instead of during the visit;





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- availability of appropriate staff for interview by teleconference, videoconference, or otherwise instead of during the visit;
- liaison with market operators and schemes to avoid duplication of work and ensure efficient utilization of competence available.

M.7.5.7.3 Management System Certification Body Accreditation

In the management system certification field, the Note to Clause 7.5.7 should be understood as follows:

Key activities include:

- Policy formulation;
- Process and/or procedure development;
- Initial approval of auditing personnel, or control of their training;
- On-going monitoring of auditing personnel;





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- Application review;
- Assignment of auditing personnel;
- Control of surveillance or recertification audits;
- Final report review or certification decision or approval.

M.7.5.7.4 Accreditation of bodies certifying person

Key activities include:

- Policy formulation and approval;
- Development and approval of processes and procedures necessary for the operation of the certification of persons systems, including requirements for selection and appointment of examiners;
- Review of applications and of contractual arrangements associated with the assessment and certification of persons;
- Development, evaluation and maintenance of the examination(s) and of re-certification;





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- Decision on certification of persons, including signing or authorization of certificates;
- Development and approval of policies, processes and procedures for the resolution of appeals and complaints received from applicants, candidates, certified persons and their employers and other parties about the certification process and criteria;
- Final decision on appeals and complaints.

M.7.5.8.1 Inspection Body accreditation

The reference to key activities in criteria M.7.5.7.1 above also applies to Clause 7.5.8.

M.7.5.9.1 Note: The *schedule* referred to in Clause 7.5.9 relates to the content of the assessment plan for a particular assessment of a CAB.





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7.6 Document and record review

M.7.6.1.1 The assessment team shall record the results of their document and record review. [Clauses 7.8.1 and 7.14.3 b) of ISO/IEC 17011 refer].

7.7 On-site assessment

M.7.7.3.1 Inspection Body accreditation

The choice of inspectors and inspections to be witnessed by the accreditation body shall be made by the accreditation body (not the inspection body), and shall take into account critical factors (e.g. new employees, the risks and the complexity of the inspection activity, physical capabilities of staff).





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See Part 2 (non-mandatory) of this document. However, it is not intended that every inspector has to be witnessed. The accreditation body should document the analysis and/or rationale used for sampling of inspectors to be witnessed to cover the scope of accreditation.

National legal requirements, regulations, standards or other relevant authority may stipulate levels of witnessing.

Any such adjustments should be made explicit in scope statements by reference to the relevant law, regulation, etc.





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7.8 Analysis of findings and assessment report

M.7.8.3.1 In Clause 7.8.3 b), *comments on competence and conformity* included in the assessment report shall be adequate to support the conclusions arising from the assessment (the CAB's fulfillment of the specified accreditation requirements) and should be adequate to support a judgment on future surveillance activities and surveillance / reassessment frequency.

M.7.8.3.2 If the report on the outcome of the assessment [Clause 7.8.3 b)] differs from the report of the findings of the assessment [Clause 7.8.3 a)], the accreditation body should provide an explanation to the assessed CAB.





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7.9 Decision-making and granting accreditation

M.7.9.4.1 The effective date of initial accreditation, as referenced in 7.9.4 e), shall be the date of or a date after the accreditation decision.

7.11 Reassessment and surveillance

M.7.11.2.1 Certification Body accreditation

As part of the surveillance procedures, accreditation bodies shall assess the performance of personnel involved in the certification process, including certification audit teams.





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7.15 Proficiency testing and other comparisons for laboratories

M.7.15.2.1 Note: The *involvement of another body* refers to competent organizations or experts outside the accreditation body that may assist the accreditation body in organizing (in full or in part) proficiency testing. For example, an accreditation body may organize calibration measurement audits using artifacts and expertise from a national metrology institute.

M.7.15.2.2 The *list of appropriate proficiency testing and other comparison programmes* should as far as possible cover the scope of laboratories accredited. It represents a collation of general practice and is not intended to be exhaustive or fixed.

M.7.15.3.1 ILAC-P9 applies.





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8. Responsibilities of the accreditation body and the CAB

8.1 Obligations of the CAB

M 8.1.1.e) Accreditation bodies shall require, where applicable, accredited CABs to have enforceable arrangements with their clients that commit the clients to provide, on request, access to accreditation body assessment teams to assess the CABs performance carrying out conformity assessment activities at the client' s site.





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8.3 Reference to accreditation and use of symbols

M.8.3.1.1 Note: The *clear indication as to which activity the accreditation related* may be accomplished by such means as:

Reference to the accreditation standard, e.g. ISO/IEC 17025 (supplemented by words and/or commonly understood abbreviations to describe either calibration or testing), ISO 15189, ISO/IEC 17020, ISO/IEC 17021 (supplemented by words and/or commonly understood abbreviations to describe the management system standard), ISO/IEC Guide 65, ISO/IEC 17024; and/or

Words and/or commonly understood abbreviations, e.g. testing (laboratory), calibration (laboratory), inspection (body), (QMS/EMS/product/personnel) certification (body); and/or

Reference to the unique accreditation number of the accredited CAB (enabling linkage to the published scope of accreditation).





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M.8.3.2.1 Certification Body accreditation

Withdrawal of an accreditation has consequences on the customers of the certification body. The *effective measures* required by Clause 8.3.2 d) shall include provisions for the withdrawal of certificates issued by certification bodies under their scope of accreditation. The accreditation body shall require the CAB to provide its customers with information on the withdrawal of its accreditation and on its consequences.

